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107 West Michigan Ave.
Kalamazoo, MI 49007

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,061,703

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,061,703, which claims a method of using the human drug product NAMENDA® (memantine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 5, 2007 (72 Fed. Reg. 31075), would be 2,336 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (4,699 \text{ days} - 630 \text{ days}) + 302 \text{ days} \\ &= 2,336 \text{ days (6.4 years)}\end{aligned}$$

Since the regulatory review period began February 7, 1990, before the patent issued (October 29, 1991), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From February 7, 1990, to and including, October 29, 1991, is 630 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,061,703

Granted: October 29, 1991

Original Expiration Date¹: April 11, 2010
Applicant: Joachim Bormann, et al.
Owner of Record: Merz Pharma GMBH & Co. KGAA
Title: Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia
Product Trade Name: NAMENDA® (memantine hydrochloride)
Term Extended: 5 years
Expiration Date of Extension: April 11, 2015

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: NAMENDA® (memantine
hydrochloride)
FDA Docket No.: 2006E-0332

Attention: Beverly Friedman